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**ELIGIBILITY DETERMINATION FOR DONORS OF HUMAN CELLS,
TISSUES, AND CELLULAR AND TISSUE-BASED PRODUCTS**

FINAL RULE

Docket No. 97N-484S

Miscellaneous Documents

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Added 6/16/04

- Busch MP, et al., "Estimation of HIV incidence in US blood donors using a novel detuned anti-HIV EIA test strategy," 5th Conf Retrovir Oppor Infect 1998; (abstract no. 531).
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retention and HIV-1 seroincidence from the HIV Network for Prevention Trials (HIVNET) Vaccine Preparedness Study (VPS). 12th World AIDS Conference . 1998. 6-28-0098.

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Reprint: Not in File

Abstract: Background: Monitoring HIV incidence (INC) in blood donors is important for (1) understanding the rate of HIV transmission in a large geographically and demographically diverse, low-risk population and (2) estimation of the transfusion risk of HIV by donations given during the pre-seroconversion (SC) window period (WP). Direct measurement of INC requires testing of serial donation samples in large donor repositories, which is logistically difficult and often limited to repeat donors. We have developed a test strategy for estimating INC that involves testing anti-HIV-pos donation samples using a modified ("detuned", DT) HIV-1 lysate EIA which, based on data from 704 donations from 114 SC panels, delays detection of SC by 129 days (95%CI: 109-149d) relative to date of SC by the same HIV-1 lysate EIA performed under standard conditions or by Western blot (WB). Methods: All WB-pos donations identified by the ARC from 1993-1996 were tested DT-EIA (Abbott 3A11 EIA: 1 :20k diln; 30 min incubs; c/o= [0.75 x pos control OD] + neg control OD). To estimate INC, the annual number of SCs was estimated ((number HIV-pos and 3A11DT-neg donations/yr) x 365d/129d), and divided by the total number of donations screened, adjusted by inter-donation interval for repeat donors. Results: INC among 1,275,449 repeat blood donors was estimated by DT-EIA at 2.95/100,000/yr (CI: 1.14-6.53/100,000/yr); this compares with an observed INC of 2.6/100,000/yr among these same donors (CI: 1.49-4.21/100,000/yr). INC among 2,717,910 first-time donors was 7.18/100,000/yr (CI: 4.51-11.2/100,000/yr) and did not change significantly between 1993 and 1996. Trends in INC by geographic regions and donor demographics will be presented. Conclusion: The DT-EIA test strategy yields a projected INC that is similar to the observed INC rate among repeat ARC donors. This approach should facilitate analysis of national INC trends, as well as focus investigation of recent SCs for HIV risk factors and viral strain characteristics

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MEETING ABSTRACTS

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INDEX MEDICUS

0 (HIV Antibodies)

- (2) Edlin BR, McCoy CB, Faruque S, Von Bargen JC, Holmberg SD. High HIV Incidence Among Young Urban Street-recruited Crack Cocaine Smokers. XI International Conference on AIDS, 1996 . 1996.

Ref Type: Abstract

Reprint: Not in File

Abstract: Background: HIV is highly prevalent among smokers of "crack" cocaine in some areas because of their high-risk sex practices. HIV incidence rates among crack smokers, however, have not been measured.

Methods: Crack smokers and nonsmokers, aged 18-29 years, were recruited from the streets of neighborhoods where drug use was prevalent in three cities, interviewed, tested for HIV antibody, and then reinterviewed and retested 6-36 months later. Using an accelerated failure-time model, we calculated HIV incidence rates for participants who were

negative on their initial HIV tests.

Results: Of 999 initially HIV-negative participants, 29 (2.9%) were HIV-positive on their follow-up tests. No seroconversions were observed among the 421 San Francisco participants. In New York and Miami, 6 of 41 injecting drug users (HIV incidence, 14%/year; 95% CI, 6.2-31) and 5 of 25 men who had sex with men (HIV incidence, 16%/year; 95% CI, 6.7-39) became positive. Excluding these groups, 16 of 326 crack smokers (4.3%/year; 95% CI, 2.6-7) and 2 of 188 nonsmokers (1.0%/year; 95% CI, 0.3-4.1) became positive; rates were similar in men and women and in the two cities. Of 117 women in New York and Miami who reported exchanging sex for money or drugs, 6 became positive (4.7%/year; 95% CI, 2.1-10.4); after controlling for this practice, cracksmoking and nonsmoking women had similar HIV incidence rates.

Conclusions: These HIV incidence rates are among the highest ever reported in the United States. HIV is being rapidly transmitted among young adults in some inner city areas through injection drug use and homosexual and heterosexual sex. Crack smokers, especially women who exchange sex for money or drugs, are at particularly high risk.

- (3) Nelson K, Strathdee S, Celentano D, Safaeian M, Macelino G, Vlahov D. Temporal Trends, Demographic and Behavioral Risk Factors for HIV Incidence Among Injection Drug Users in Baltimore. *Am.J.Epidemiol.* 149[11], S10. 1999.
Ref Type: Abstract

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Abstract: We evaluated the temporal trends, behavioral and demographic risks for HIV incidence in a cohort of about 1500 HIV negative injection drug users (IDUs) in Baltimore recruited by street outreach in 1988-89; only about 15% were in drug treatment at enrollment. Follow-up was at 6 month intervals. Overall 296 seroconverters (SC) occurred in 9322.27 persons yrs (pyrs) of follow-up, incidence = 3.10/100 pyrs. The incidence was highest in 1988-89, 4.46/100 pyrs, declined to 3.68/100 pyrs in 1990-92, to 2.52/100 pyrs in 1993-95 and to 1.98/100 pyrs in 1996-97. Incidence was highest in young (~35 yrs) females who injected drugs in the prior 6 months, 5.5/100 pyrs; followed by young male active drug injectors = 5.0/100 pyrs. Subjects who stopped active drug use in the recent interval had HIV incidence of 1.1/100 pyrs (135 yr old males), 1.6/100 pyrs (2 35 yr old females), 2.3/100 pyrs (<35 yr old males). The relative HIV incidence among active vs. inactive IDU's in the prior 6 months was 2.1 (95%CI = 1.54, 2.91) and younger (~35 yrs) vs older IDU's was 1.95 (95%CI = 1.49, 2.55). Although the HIV incidence has declined in this cohort of mostly out of treatment IDUs in Baltimore recently, younger drug users who continue to inject drugs remain at high risk of HIV infection. More widespread and effective efforts to prevent HIV in these young IDUs, by decreasing or eliminating high risk drug injection practices, especially in younger IDUs, are critically needed.

- (4) Seage GRI, Holte S, Buchbinder S, Koblin B, Celumb C. Feasibility of conducting HIV-1 vaccine trials in the United States: Recruitment, retention and HIV-1 seroincidence from the HIV Network for Prevention Trials (HIVNET) Vaccine Preparedness Study (VPS). 12th World AIDS Conference . 1998. 6-28-0098.
Ref Type: Abstract

Reprint: Not in File

Abstract: Background: The VPS was a prospective cohort study designed to recruit, retain and estimate HIV-1 incidence over time under, with responsible and achievable risk reduction counseling. Methods: Crude HIV-1 incidence rates and 95%CI were calculated for socio-demographic, site, and eligibility criteria (any anal intercourse in the past year for MSM, any injection in the past 6 months for IDU or any of 6 behavioral eligibility criteria among women (WSM)). Adjusted RR were estimated using a Poisson regression. Results: 4892 (3257 MSM, 770 male IDU, 354 female IDU, 511 WSM) participants were

recruited in 8 US cities from 4/94-1/94 using the following approaches: 40%rollover from existing cohorts, 21% "snowball" techniques, 20%staff outreach, 14%media, and 4%other. At 18 months, 88%follow-up was achieved and 89 incident HIV-1 infections (1.36/100 PY, 95%CI =1.07-1.61) were observed. HIV-1 seroincidence rates varied by baseline eligibility criteria with rates of 1.54/100 PY (95%CI =1.22-1.94) among MSM, 0.38/100 PY (95%CI =0.15-1.01) among Male IDUs, 1.15/100 PY (95%CI =0.57-2.29) among WSM and 1.26/100 PY (95%CI =0.57-2.80) among female IDU's; and enrollment site, from 0.49/100 PY (95%CI =0.19-1.30 to 2.18/100 PY, 95%CI =1.46-3.25). Participants who were definitely willing to enroll in an HIV vaccine trial had the highest seroincidence (1.97/100 PY, 95%CI =1.41-2.74). Varying baseline eligibility among women to include 3 or more high risk sexual behaviors (2.00/100 PY, 95%CI =0.91-3.71) or crack use (1.70/100 PY, 95%CI =0.93-2.80) and MSM to include only unprotected anal intercourse (1.98/100 PY, 95%CI =1.51-2.60) resulted in higher HIV-1 incidence. After adjusting for eligibility, no non-site significant differences in HIV-1 seroincidence were observed.

Conclusions: MSM and women at heterosexual/injection risk, with some eligibility modifications, can be rapidly recruited, enrolled and followed under conditions comparable to a preventive HIV vaccine trial. New recruitment using revised eligibility criteria are currently being conducted to recruit male IDU's with higher HIV-1 incidence. HIV-1 seroincidence is dynamic and affected by both treatment and prevention efforts. Continued efforts will be needed to monitor HIV-1 seroincidence in order to plan for efficacy trials.